CLAIMS:

1. An actuator for a heart assist device, the actuator including:

an inflatable balloon having a first body portion, a second body portion and a flexure region joining the first and second body portions; and

a shroud or wrap adjacent the first body portion and having a peripheral extent at least equal to the peripheral extent of the balloon flexure region;

wherein the balloon and the shroud or wrap are shaped such that the shroud or wrap restrains a part of the balloon first body portion at or near the flexure region against displacement towards the shroud or wrap past a predetermined limit but allows unrestrained displacement away from the shroud or wrap.

2. The actuator as claimed in claim 1, wherein the balloon and the shroud are shaped such that the shroud restrains said part of the balloon first body portion at or near the flexure region against outward displacement during inflation of the balloon but allows unrestrained inward displacement during deflation.

3. The actuator as claimed in claim 1 or 2, wherein, during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn against at least part of the inner surface of the balloon first body portion.

4. The actuator as claimed in claim 1, 2 or 3, wherein the shroud is generally inwardly concave.

5. The actuator as claimed in claim 4, wherein the shroud is elongated and elliptical.

6. The actuator as claimed in any one of the preceding claims, wherein the first body portion, second body portion and flexure region are integrally formed.

7. The actuator as claimed in claim 6, wherein the first body portion, second body portion and flexure region are integrally formed by dip moulding.

8. The actuator as claimed in any one of the preceding claims, wherein the actuator also includes a bushing adapted for connection to a motive power source.

9. The actuator as claimed in claim 8, wherein the balloon also includes a neck portion joined to the first portion, the neck portion being adapted for sealing connection with the bushing.

10. The actuator as claimed in claim 9, wherein the shroud also includes a neck portion adapted for sealing connection with the balloon neck portion.

11. An actuator for a heart assist device, the actuator including:

a bushing adapted for connection to a hydraulic or pneumatic power source; and

an inflatable balloon having a narrower neck portion adapted for sealing connection with the bushing exterior, wider first and second body portions and an arcuate flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being inwardly concave when the balloon is inflated and generally outwardly concave when the balloon is deflated.

12. The actuator as claimed in claim 11, wherein the device also includes a shroud or wrap having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions.

13. The actuator as claimed in claim 12, wherein the balloon and the shroud or wrap are shaped such that a part of the balloon first body portion at or near the flexure region is restrained against outward displacement past a predetermined limit by the shroud or wrap but unrestrained against inward displacement.

14. The actuator as claimed in claim 13, wherein during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn directly against at least part of the inner surface of the balloon first body portion.

15. A heart assist device including:

a hydraulic or pneumatic power source; and

an actuator including:

a bushing adapted for operative connection to the motive power source;

an inflatable balloon having a narrower neck portion adapted for sealing connection with the bushing exterior, wider first and second body portions and a flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being generally inwardly concave when the balloon is inflated and generally outwardly concave when the balloon is deflated; and

a shroud or wrap having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions,

wherein the balloon and the shroud are shaped such that a part of the balloon first body portion at or near the flexure region is restrained against outward displacement by the shroud past a predetermined limit but unrestrained against inward displacement.

16. The device as claimed in claim 15, wherein, during inward

displacement, at least part of the inner surface of the balloon second body portion is able to be drawn against at least part of the inner surface of the balloon first body portion.

17. The device as claimed in claim 15 or 16, wherein the balloon and shroud are shaped such that substantially all of the balloon first body portion is restrained against outward displacement by the shroud and unrestrained against inward displacement.

18. The device as claimed in claim 15, 16 or 17, wherein the heart assist device is configured for extra-aortic counter-pulsation and the balloon is positioned on the exterior of an arterial vessel.

19. The device as claimed in claim 15, 16 or 17, wherein the heart assist device is configured for use as an interposition graft in which the device replaces a completely resected section of the aorta.

20. The device as claimed in claim 15, 16 or 17, wherein the heart assist device is configured for use as an aortic patch in which an aperture is formed in the aorta which is filled with the heart assist device.

21. The device as claimed in any one of claims 15 to 20, wherein, when the balloon is inflated, the flexure region has a radius of curvature of at least 0.1 mm.

22. The device as claimed in claim 21, wherein, when the balloon is inflated, the flexure region has a radius of curvature of approximately 1.0 mm.

23. The device as claimed in claim 22, wherein, when the balloon is inflated, the flexure region has a radius of curvature of approximately 3.0 mm.

24. The device as claimed in any one of claims 15 to 23, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is no more than approximately 4:1.

25. The device as claimed in any one of claims 15 to 23, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is approximately 3:1

26. The device as claimed in any one of claims 15 to 23, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is approximately 2:1

27. The device as claimed in any one of claims 15 to 26, wherein the bushing has an inlet/outlet bore.

28. The device as claimed in claim 27, wherein the bore also includes one or more internal restrictions adapted to prevent suction of the balloon into the bore.

29. The device as claimed in anyone of claims 15 to 28, wherein the balloon is formed from silicone, polyurethane or a polyurethane-polysiloxane block co-polymer.

30. The device as claimed in any one of claims 15 to 29, wherein the balloon is formed by mandrel dipping.

31. The device as claimed in any one of claims 15 to 30, wherein the balloon is formed by dipping a suitably shaped mandrel into the polymer and allowing a thin coating of the polymer to cure on the mandrel.

32. The device as claimed in claim 31, wherein the balloon is made of 2 to 4 coatings of the polymer.

33. The device as claimed in claim 32, wherein the balloon a total thickness of 150-300 microns.

34. The device as claimed in any one of claims 15 to 33, wherein the balloon neck portion is a snug sealing fit over the bushing exterior.

35. The device as claimed in claim 34, wherein the shroud or wrap has a neck portion that is a snug sealing fit over the balloon neck portion.

36. The device as claimed in claim 35, wherein the bushing has a slightly tapered neck portion adapted for engagement with the balloon neck portion.

37. The device as claimed in claim 36, wherein the bushing neck portion has a converging taper in the direction of the balloon.

38. The device as claimed in any one of claims 15 to 37, wherein the balloon is held in place on the aorta by a flexible wrap which extends about the aorta and bears against the first body portion of the balloon or a shroud mounted thereon.

39. The device as claimed in claim 38, wherein the flexible wrap is shaped to fit the second body portion of the balloon.

40. The device as claimed in claim 39, wherein the flexible wrap is also shaped to fit the neck portion.

41. The device as claimed in claim 38, 39 or 40, wherein the flexible wrap is inelastic or slightly elastic so that its stretch and flexibility characteristics substantially match those of the native aorta.

42. A flexible inflatable balloon for a blood displacing heart assist device, the balloon including:

a neck portion having first and second ends;

a substantially annular first body portion connected at its inner periphery to the neck portion second end; and

a substantially oval or circular second body portion connected at its outer periphery to the outer periphery of the first body portion,

the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion adapted to maintain a radius of curvature during movement of the second body portion between inwardly concave and outwardly concave during deflation and inflation of the balloon respectively.

43. The balloon as claimed in claim 42, wherein the balloon is formed as a single piece.

44. The balloon as claimed in claim 42 or 43, and further including a shroud adapted to overlie and abut the annular first body portion of the balloon.

45. The balloon as claimed in claim 44, wherein the shroud is shaped such that the shroud restrains said portion of the balloon at or near the flexure region against outward displacement during inflation of the balloon but allows unrestrained inward displacement during deflation.

46. The balloon as claimed in claim 44 or 45, wherein the shroud is generally inwardly concave

47. The balloon as claimed in claim 46, wherein the shroud is elongated, and elliptical.

48. The balloon as claimed in any one of claims 44 to 46, wherein the shroud also includes a neck portion adapted for sealing connection with the balloon neck portion.

49. The balloon as claimed in claim 48, wherein the shroud is adapted to facilitate bonding of a wrap to the first body portion of the balloon.

50. The balloon as claimed in any one of claims 42 to 49, and further including a bushing adapted for connection to a hydraulic or pneumatic power source.

51. The balloon as claimed in claim 50, wherein the bushing is formed with internal restrictions such as flutes, ribs, or secondary lumens to prevent the balloon being sucked into the bushing during deflation of the balloon.

52. The balloon as claimed in claim 50or 51, wherein the neck portion of the balloon is adapted for sealing connection with the bushing.

53. The balloon as claimed in claim 50, 51 or 52, wherein the bushing has a taper adapting the relatively large diameter of the neck of the balloon to the relatively

small diameter of a hydraulic or pneumatic fluid line connecting the balloon to a power source.

54. The balloon as claimed in claim 53, wherein this taper is elongated to enhance the flexibility of the bushing along its central axis.

55. The balloon as claimed in any one of claims 42 to 54, wherein the balloon has in its longitudinal plane, a gentle arc of the order of radius of 150-300mm.

56. An actuator for a heart assist device, the actuator including:

a flexible inflatable balloon having a neck portion connected at one end to a bulbous body portion having a first side and a second side; and

a substantially inelastic shroud or wrap having a flared portion that extends over the adjacent first side of the balloon bulbous portion,

wherein, during deflation, the second side of the bulbous body portion is able to be drawn against the first side of the bulbous body portion.

57. The actuator as claimed in claim 56, wherein the shroud or wrap supports the first side of the balloon bulbous portion against substantial movement whilst the second side of the balloon bulbous portion is free to move during inflation and deflation.

58. A method of providing extra-aortic heart assistance using the actuator claimed in any one of claims 1 to 10, 11 to 14 or 56 or 57, or the heart assist device claimed in any one of claims 15 to 41, or the balloon claimed in any one of claims 40 to 51, the method including mounting the balloon second body portion adjacent the exterior of an arterial vessel.

59. A method of providing intra-aortic heart assistance using the actuator claimed in any one of claims 1 to 10, 11 to 14 or 56 or 57, or the heart assist device claimed in any one of claims 15 to 41, the method including resecting a portion of an arterial vessel and mounting the balloon with the balloon second body portion sealingly replacing the resected arterial portion.